SECTION 5 – 510K Summary

K081029

SEP 1 2 2008

Fisher & Paykel HEALTHCARE

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Contact person	James Thompson
Date prepared	4 April 2008
Trade name	Sleepstyle™ 200 Auto Series HC254
Common name	Auto CPAP Humidifier
Classification name	Non continuous ventilator IPPB, Class II (21 CFR § 868.5905, product code BZD)
Predicate devices	K040941 Fisher & Paykel Healthcare HC234 CPAP Humidifier
Establishment Registration	9611451

5.1 Description

The Sleepstyle™ 200 Auto Series HC254 is a non-invasive auto-adjusting Continuous Positive Airway Pressure (CPAP) flow generator, incorporating a heated respiratory humidifier.

The HC254 is comprised of two functional units. One is a motorised fan assembly that provides positive air pressure. The fan speed is directly related to air pressure, and is controlled by software. The blower assembly output connects directly to a humidification chamber at the front of the device.

The second functional unit of the HC254 is a heated passover humidifier. The water is contained in a humidification chamber positioned on a heaterplate at the front of the unit. The chamber connects directly to the blower assembly via a port at the back of the chamber. Ambient temperature is monitored in order to reduce breathing tube condensation in cooler operating conditions.

The Sleepstyle™ 200 Auto Series HC254 detects apneas, hypopneas, and flow-limitation. To this end the HC254 contains a breath detection algorithm and event detection algorithms. The apnea and hypopnea detection algorithms are time-domain based algorithms that compare the patients breathing and/or flow to thresholds dependent on the patient's peak inspiratory flow. The flow-limitation detection algorithm analyzes the patients breathing in the frequency domain and determines the presence or absence of flow-limitation.

The HC254 also contains an algorithm, called SensAwake™, that is capable of detecting breathing patterns that are indicative of the "anxious" awake state. If SensAwake™ detects this "anxious" awake state then the pressure is reduced to help facilitate the patients return to sleep.

An available treatment efficacy reporting software accessory is PerformanceMaximizer™. The package offers detailed reporting on therapy effectiveness, including compliance, AHI, leak and pressure. The supplied SmartStick™ fitted at the rear of the device transfers this information via USB technology.

5.2 Intended Use

The Sleepstyle™ 200 Auto Series HC254 is for use on adult patients for the treatment of Obstructive Sleep Apnea (OSA). The device is for use in the home or sleep laboratory.

5.3 Technological Characteristics Comparison

The Sleepstyle™ 200 Auto Series HC254 is substantially equivalent to the Fisher & Paykel Healthcare HC234 in terms of intended use, operating principle, fundamental technological characteristics and manufacturing process.

Differences between the Sleepstyle™ 200 Auto Series HC254 and the predicate devices include;

- Introduction of software algorithms for detecting and responding to apneas, hypopneas, and flow-limitation.

- New SensAwake™ algorithm for detecting breathing patterns indicative of the "anxious" awake state.

- New PerformanceMaximizer™ efficacy reporting software accessory.

- SmartStick removal storage media device for data analysis.

- Pressure adjustment for leak compensation.

5.4 Non-Clinical Tests

Non-clinical testing of the Sleepstyle™ 200 Auto Series HC254 has been carried out covering mechanical, electrical and thermal safety, environmental conditions, electromagnetic compatibility, functional verification and performance. Copies of these test reports are included in Appendix E and are outlined in section 18 of this submission.

The Sleepstyle™ 200 Auto Series HC254 complies with the requirements of IEC 60601-1 Electrical Safety, IEC 60601-1-2 EMC and 17510-1 Sleep Apnea Therapy Devices. Copies of these test reports are included in Appendix D.

5.5 Clinical Tests

Clinical testing of the Sleepstyle™ 200 Auto Series HC254 demonstrated the safety of the device by a lack of adverse events, while efficacy of treatment was shown by a reduction of the obstructive indices to below 15/hour, improvement in oxygen saturation <90%, and reduction of arousal index from baseline. A clinical study report is included in appendix F.

5.6 Conclusion

Testing carried out on the Sleepstyle™ 200 Auto Series HC254 indicates that it meets design and performance functional requirements. The proposed device meets the requirements of sleep apnea breathing therapy device standards for safety and performance.

This information indicates that the Sleepstyle™ 200 Auto Series HC254 is substantially equivalent to the predicate device in terms of safety, effectiveness and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

Mr. James Thompson
Regulatory Affairs Manager
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P.O. Box 14 348, Panmure
Auckland
NEW ZEALAND

Re: K081029
Trade/Device Name: Sleepstyle™ 200 Auto Series HC254
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 5, 2008
Received: September 5, 2008

Dear Mr. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

SECTION 4 – Indications for Use Statement

510(k) Number:

Device Name: Sleepstyle™ 200 Auto Series HC254

Indications for Use:

The Sleepstyle™ 200 Auto Series HC254 is for use on adult patients for the treatment of Obstructive Sleep Apnea (OSA). The device is for use in the home or sleep laboratory.

Prescription Use ✓ (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (DE)

W. Maly for M. Hoshaud

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081029